EXCIMER LASER IN-SITU KERATOMILEUSIS (LASIK) UNDER A CORNEAL FLAP FOR MYOPIA OF 2 TO 20 D*

BY *Tarek Salah*, MD (BY INVITATION), *George O. Waring III*, MD, *Akef El-Maghraby*, MD (BY INVITATION), *Ken Moadel*, MD (BY INVITATION), AND *Suzan B. Grimm*, OD (BY INVITATION)

ABSTRACT

Background: We report the results of a recent technique of keratomileusis for myopia: excimer laser in-situ keratomileusis (LASIK).

Methods: We studied retrospectively 88 eyes of 63 patients that received LASIK with the Chiron Automated Corneal Shaper and the Summit OmniMed excimer laser under a hinged corneal flap without sutures.

Results: Mean follow-up was 5.2 months. Mean spherical equivalent of the manifest refraction before surgery was -8.24 diopters (D)(range -2.00 to -20.00 D). Mean spherical equivalent refraction after surgery was +0.22 D (SD, 1.42 D). Of 40 eyes with a baseline refraction from -2.00 to -6.00 D, 25 (63%) had a refraction within ±0.50 D and 37 eyes (93%) within ±1.00 D. In 29 eyes with baseline refraction of -6.12 to -12.00 D, postoperative refraction was within ±1.00 D in 19 (65%). In 19 eyes with baseline refraction of -12.10 to -20.00 D postoperative refraction was ±1.00 D in 8 (43%). Overall, 64 of 88 eyes (72.8%) had a refraction within ±1.00 D after surgery. Between three weeks and five months after surgery the change in the mean spherical equivalent refraction was -0.61 D in the myopic direction. Uncorrected visual acuity after surgery was 20/20 or better in 31 eyes (36%) and 20/40 or better in 61 eyes (71%). Three eyes (3.6%) lost two lines or more of spectacle corrected visual acuity, two from progressive myopic maculopathy and one from irregular astigmatism. No eyes had vision threatening complications.

Conclusion: Excimer laser in-situ keratomileusis (LASIK) under a corneal flap can be an effective method of reducing myopia between -2.00 to -20.00 D, with minimal complications. Current surgical algorithms need modification to improve predictability. Stability of refraction after surgery requires further study.

* From the El Maghraby Eye Hospital, Jeddah, Saudi Arabia. The Al-Noor Foundation provided funding for this project. Dr Waring is a consultant for Summit Technology and for Chiron Vision.

INTRODUCTION

Keratomileusis has developed through the following series of improving techniques since it was first performed in humans in 1963 by Jose Barraquer[1]: cryolathe keratomileusis on the disc of Barraquer,[2] manual in-the-bed keratomileusis of Pureskin,[3] planar nonfreeze keratomileusis with the BKS 1000 instrument of Krumeich,[4] keratokyphosis of Hoffmann,[5] Ruiz in situ keratomileusis with a manual microkeratome or an automated microkeratome (also called automated lamellar keratoplasty [ALK] for myopia),[6,7] excimer laser keratomileusis on the disc of Buratto (also called photokeratomileusis [PKM] or intrastromal keratomileusis),[8] and excimer laser in situ keratomileusis (LASIK) under a flap of Pallikaris.[9,10] We have discussed the details of the development and the advantages and disadvantages of excimer laser in situ keratomileusis previously.[11] Here, we present the results of a retrospective series of 88 myopic eyes treated with LASIK. At the time of this writing, there were no articles in the peer-reviewed literature on LASIK.

PATIENTS AND METHODS

DESIGN OF STUDY

We studied retrospectively the records of patients who received excimer laser in situ keratomileusis (LASIK) for myopia at the El Maghraby Eye Hospital in Jeddah, Saudi Arabia between November 1993 and March 1994. Operations were done by two surgeons (T.S., G.W.) who had extensive past experience in refractive surgery.

In conjunction with the Center for Clinical Research, Chicago we developed standardized forms for data recording. The Center received the forms from the hospital, edited and entered the data into the FoxPro database, and performed analyses with the SAS program.

PATIENT SELECTION

All patients were at least 18 years of age. Eyes had a spherical equivalent of the manifest refraction from -2.00 D to -20.00 diopters (D) and refractive astigmatism of 5.00 D or less. Exclusion criteria included prior refractive surgery, active ocular disease, keratoconus, keratoconus suspected on videokeratography, connective tissue disorders, and pregnancy. There were no limits on baseline visual acuity.

POPULATION REPORTED

Between November 1993 and March 1994, a total of 337 eyes of 196 patients received LASIK. We omitted the following patients from this study: (1) the 25 who did not return for follow-up, many because they travelled internationally for surgery and had follow-up in other countries; (2) the 73

patients with only one follow-up examination at 2 weeks or less; and (3) the 35 patients with less than 90 days' follow-up. Thus, the final population of 63 patients (88 eyes) (32% of the total patients) included all who had one or more follow-up examinations at 90 days or more after surgery.

Patients ranged in age from 15 to 59 years (mean, 25.8; SD, 8.2). Sixty patients (95.2%) were males. We divided the eyes into the following baseline groups determined by the spherical equivalent of the manifest refraction[12]: lower, -2.00 to -6.00 D (40 eyes); middle, -6.12 to -12.00 D (29 eyes); and higher, -12.12 to -20.00 D (19 eyes).

CLINICAL EXAMINATIONS

All eyes had a complete ophthalmic examination before surgery; this included slit-lamp microscopy, applanation tonometry, indirect ophthalmoscopy, and manifest refraction by an optometrist or ophthalmologist. Videokeratography (Tomey - Computed Anatomy Topographic Modeling System version 1.51, New York, or EyeSys Corneal Analysis System version 2.104, Houston, Texas) was done before and after surgery, and the results will be reported separately. For each patient, all examinations were done in the same 10-foot lane with the same equipment. Visual acuity was measured using a projected tumbling E chart (20/20 to 20/400) standardized by the Saudi Arabian Ophthalmologic Society. The smallest line in which the patient could identify three of four E's was recorded as the final visual acuity.

SURGICAL NOMOGRAMS

Two different approaches to calculating the diameter and depth of ablation were used. The first, used in 16 eyes, consisted of Summit photorefractive keratectomy (-2.00 D to -9.99 D) or myopic keratomileusis (-10.00 D to -20.00 D) programs, in which the spherical equivalent of the manifest refraction corrected to a vertex distance of 12.0 mm and a 6.0 mm diameter ablation zone was entered into the Summit computer.

The second approach, used in 56 eyes, was the Salah-LASIK nomogram (see Appendix), a modification of the original Ruiz keratomileusis in situ nomogram for myopia. The modifications were based on our initial informal clinical experience using the Ruiz nomogram for the LASIK procedure, which produced consistent overcorrections. In the Salah-LASIK nomogram, the spherical equivalent of the manifest refraction without correction for the vertex distance was used to determine the depth and diameter of ablation; both these variables were then entered into the Summit computer to determine the dioptric correction that the computer calculated would be achieved by the specific depth and diameter. That dioptric power — not the actual refraction of the eye — and the diameter of ablation from the Salah-LASIK nomogram were entered into the Summit computer for surgery. Ablation diameters ranged from 4.5 to 5.0 mm and

APPENDIX

Salah-LASIK Nomogram, Version 1993, used in 64% of eyes in this study*
Summit OmniMed Excimer Laser, flap diameter 7.2 to 7.4 mm, flap thickness 160 μm

Spherical Equivalent Spectacle Refraction (D)	Ablation Zone Diameter (mm)	Ablation Depth (μm)
- 2.00	5.0	21
- 2.50	5.0	25
- 3.00	5.0	29
- 3.50	5.0	33
- 4.00	5.0	39
- 4.50	5.0	43
- 5.00	5.0	45
- 5.50	5.0	48
- 6.00	5.0	51
- 6.50	5.0	57
- 7.00	5.0	63
- 7.50	5.0	66
- 8.00	5.0	69
- 8.50	5.0	71
- 9.00	5.0	74
- 9.50	5.0	77
-10.00	5.0	80
-10.50	5.0	82
-11.00	5.0	85
-11.50	5.0	88
-12.00	5.0	91
-12.50	5.0	93
-13.00	5.0	96
-13.50	5.0	101
-14.00	5.0	106
-14.50	5.0	111
-15.00	5.0	116
-15.50	4.7	103
-16.00	4.7	106
-16.50	4.7	108
-17.00	4.7	110
-17.50	4.7	112
-18.00	4.7	116
-18.50	4.5	109
-19.00	4.5	111
-19.50	4.5	115
-20.00	4.5	118

*The other 36% had a 6.0 mm ablation zone using the summit PRK algorithm programmed in the laser. Revised nomogram is undergoing clinical testing.

central depths from 30 to 105 μm. Because of the small number of eyes in the Summit algorithm group and the disparate ranges of refraction treated with the two methods, statistical comparison of the results was not possible.

SURGICAL TECHNIQUE

The Summit OmniMed Laser (Summit Technology, Waltham, Mass) had the following variables: wavelength 193 nm; radiant exposure (fluence) 180 mJ/cm^2; repetition rate 10 Hz; maximum ablation diameter 6.5 mm; and proprietary software that determined the number of laser pulses and the rate and number of steps of opening of the diaphragm mask. The instrument was calibrated before each surgical session by ablating a photographic filter 100 μm thick (550 to 650 pulses for initial perforation, additional 225 to 275 pulses for 90% removal). Ablation of a Polaroid film allowed visual estimation of the uniformity of energy distribution. Periodically, a plastic disc was ablated and sent to the manufacturer, where it was scanned for proper depth, contour, and smoothness.

The microkeratome was the Automated Corneal Shaper (Chiron Vision, Irvine, Calif), sequence number 54 or 59A (refurbished). The adjustable suction ring was set at its lowest height to create an anterior corneal flap 7.2 to 7.4 mm in diameter. The 160 base plate was designed to cut a corneal flap 160 μm thick. The microkeratome was assembled and tested preoperatively according to the manufacturer's instructions (Casebeer JC. *A Comprehensive System of Refractive Surgery: Automated Laser Lamellar Keratoplasty*. Chiron Vision, Irvine, Calif, 1993). The blades had a black dot on the front side, and the surgeons judged the cutting quality variable.

The center of the pupil was marked with a Sinskey hook and the cornea with a Ruiz marker; the suction ring was centered around these marks, and suction was applied with 25 cm Hg. The intraocular pressure was verified as being greater than 65 mm Hg by a Barraquer applanation tonometer, and the diameter of the disc as being 7.2 mm or greater by a calibrated applanating lens. The microkeratome advanced across the cornea by gears on a track and was stopped by visual inspection by one surgeon and by an automatic stopper by the other surgeon to leave a 30° long, 1-mm wide hinge of tissue. The microkeratome was removed from the suction ring, leaving the flap in place. The suction was stopped, but the ring was left in place to steady the eye. The helium neon aiming beams of the laser were focused on the cornea and were centered so that they intersected the 3- and 9-o'clock locations at the edge of the pupil. The flap was folded back with a canula or a pair of toothless forceps. A spherical excimer laser ablation was carried out in the stromal bed; no correction of astigmatism was attempted. The surface of the bed and disc were moistened with balanced salt solution, and the flap was folded back onto the cornea using a cannula. The edge of the flap was dried for 3 to 5 minutes with microsponges (without blow-drying) to ensure good adhesion between the flap and the bed as indicated by stress lines radiating into the flap when the limbus was depressed. Figures 1

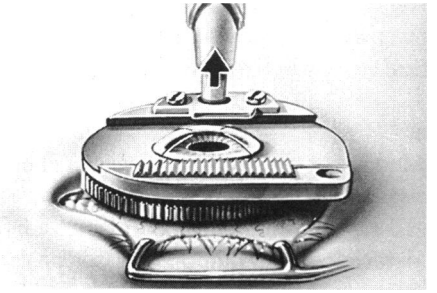

FIGURE 1

LASIK technique. Eyelashes are sequestered beneath an adhesive drape. Four-radial marker (or alternately, Ruiz marker) creates alignment lines on cornea. Suction ring is applied to globe (arrow) and set to create corneal flap 7.2 to 7.5 mm in diameter.

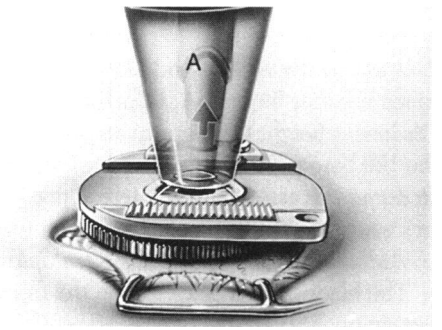

FIGURE 2

LASIK technique. Intraocular pressure is verified as greater than 65 mm Hg with applanation tonometer.

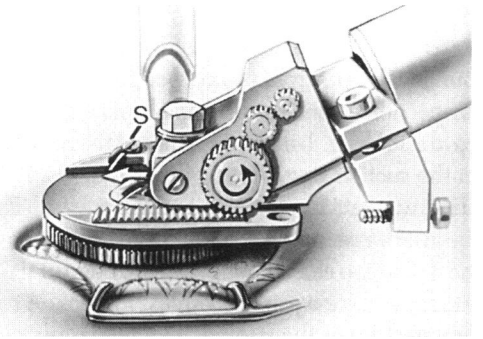

FIGURE 3

LASIK technique. Surgeon inserts microkeratome (with baseplate that creates 160 μm thick flap) into dovetail of suction ring and advances it forward (large arrow) with gear mechanism (circular arrow) until edge of blade is aligned with screw head (S), at which point stopper screw halts forward advance of microkeratome.

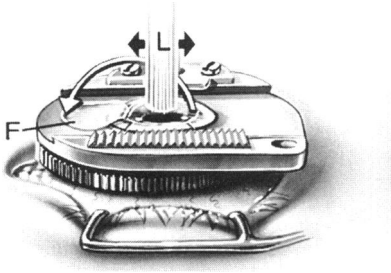

FIGURE 4
LASIK technique. Surgeon turns off suction, steadies eye with suction ring, turns back corneal flap (F), focuses, and centers the excimer laser (L) that ablates bed with expanding diaphragm (small arrows) to correct myopia.

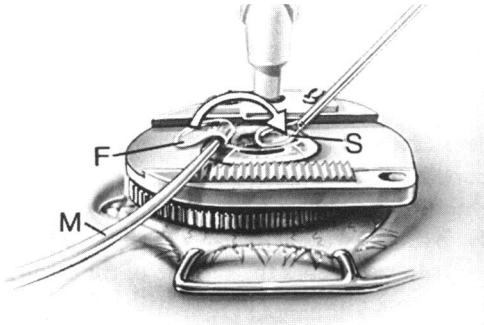

FIGURE 5
LASIK technique. Surface of bed is flooded with balanced salt solution (S) and flap (F) is flipped with blunt instrument (M) back into place, where it floats properly aligned onto bed.

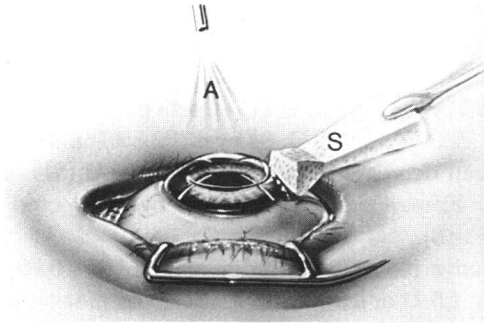

FIGURE 6
LASIK technique. Microsponge (S) removes fluid from edge of flap. Filtered humidified oxygen (A) is blown onto cornea for approximately 30 seconds from distance of approximately 6 inches, securing flap without sutures. (No air drying was used in eyes described in this paper).

through 6 summarize the surgical procedure. Topical chloramphenicol or tobramycin was prescribed, 4 times daily for 5 days. No corticosteroids, nonsteroidal anti-inflammatory drugs, or oral analgesics were used after surgery.

The refractive goal was emmetropia in all eyes.

RESULTS

FOLLOW-UP EXAMINATIONS

Although patients were given follow-up appointments for 24 to 48 hours, 2 weeks, and 1, 3, 6 and 12 months, follow-up was erratic, a reflection of cultural norms in the Middle East. For refractive and visual acuity outcome analysis, we report the results between 91 and 253 days (3 to 8 months; mean, 158 days [5.2 months]; SD, 38.6 days). Follow-up times at which the 88 eyes of the 63 patients were examined were: 90 to 120 days, 22 patients (25% of eyes); 121 to 180 days, 34 patients (39% of eyes); 181 to 210 days, 29 patients (33% of eyes); 211 to 253 days, 3 patients (3% of eyes).

POSTOPERATIVE APPEARANCE OF CORNEA

Slit-lamp microscopy done 24 to 48 hours after surgery showed the flap to be normal or slightly edematous. The bed and the edge of the flap were difficult to identify. By 1 to 2 weeks the flap was clear and difficult to distinguish from the bed. In some eyes the outline of the laser ablation in the stromal bed could be seen, especially in eyes with larger corrections. By 6 to 8 weeks, a circular gray scar appeared around the edge of the disc where the epithelium was in contact with the stroma. Faint punctate grey spots appeared in the bed, which were interpreted clinically as focal "healing spots," either deposits of extracellular matrix or large keratocytes; these persisted for months.

REFRACTIVE OUTCOME

The mean refractive outcome was +0.22 D (SD, 1.42; range -3.62 to +6.75 D) (Table I, Figs 7 and 8). Ranges of refractive outcome were as follows: ±0.50 D, 47 eyes (53.4%); ±1.00 D, 64 eyes (72.8%); and ±2.00 D, 80 eyes (90.9%). The mean decrease in myopia was -8.46 D (SD, 4.85 D; range, 2.12 to 25.50 D). Fifteen eyes (17.1%) were overcorrected by more than 1.00 D (Table I, Fig 8).

The preoperative refractive cylinder ranged from 0.00 to 4.00 D, 75 eyes (85%) having 1.5 D or less. After LASIK, the mean change in refractive cylinder was a decrease of 0.25 D (SD, 0.64 D; range, increase of 1.25 D to decrease of 2.00 D) (Table II). The mean surgically induced refractive cylinder determined by vector analysis using the Naylor method[13] was 0.81 D (SD, 0.86; range 0 to 5.66 D) (Table III). The mean final refractive astigmatism was 0.70 (SD, 0.72; range, 0.00 to 4.00 D)(Table IV).

TABLE I: REFRACTION AT BASELINE AND AT MEAN OF 5 MONTHS AFTER LASIK IN 88 MYOPIC EYES

SPHERICAL EQUIVALENT MANIFEST REFRACTION (D)	BEFORE SURGERY NO. EYES	(%)	AFTER SURGERY NO. EYES	(%)
+6.12 to +6.75			1	(1.1)
+3.12 to +6.00			1	(1.1)
+2.12 to +3.00			3	(3.4)
+1.12 to +2.00			9	(10.3)
+0.62 to +1.00			11	(12.5)
+0.12 to +0.50			18	(20.5)
0.00 to - 0.50			29	(33.0)
- 0.62 to - 1.00			6	(6.8)
- 1.12 to - 2.00			7	(8.0)
- 2.12 to - 3.00	2	(2.3)	1	(1.1)
- 3.12 to - 4.00	10	(11.4)	0	(0.0)
- 4.12 to - 5.00	16	(18.2)	2	(2.2)
- 5.12 to - 6.00	12	(13.6)		
- 6.12 to - 9.00	17	(19.3)		
- 9.12 to -12.00	12	(13.6)		
-12.12 to -16.00	11	(12.5)		
-16.12 to -20.00	8	(9.0)		
Total	**88**	**(100)**	**88**	**(100)**
±0.50	0		47	(53.4)
±1.00	0		64	(72.8)
Mean(SD)	-8.24	(4.43)	+0.22	(1.42)

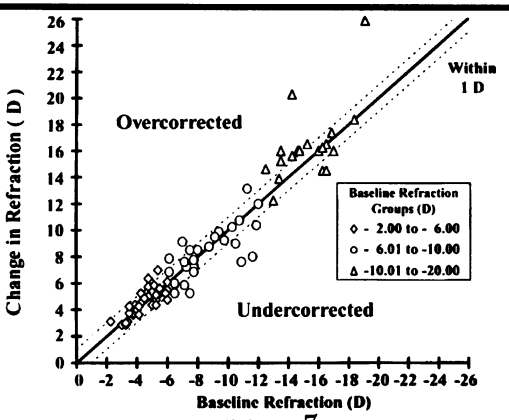

FIGURE 7

Scattergram displaying spherical equivalent of manifest refraction in three baseline refraction groups (D) at mean of 5 months after LASIK in 88 eyes. Dotted lines indicate ±1.00 D.

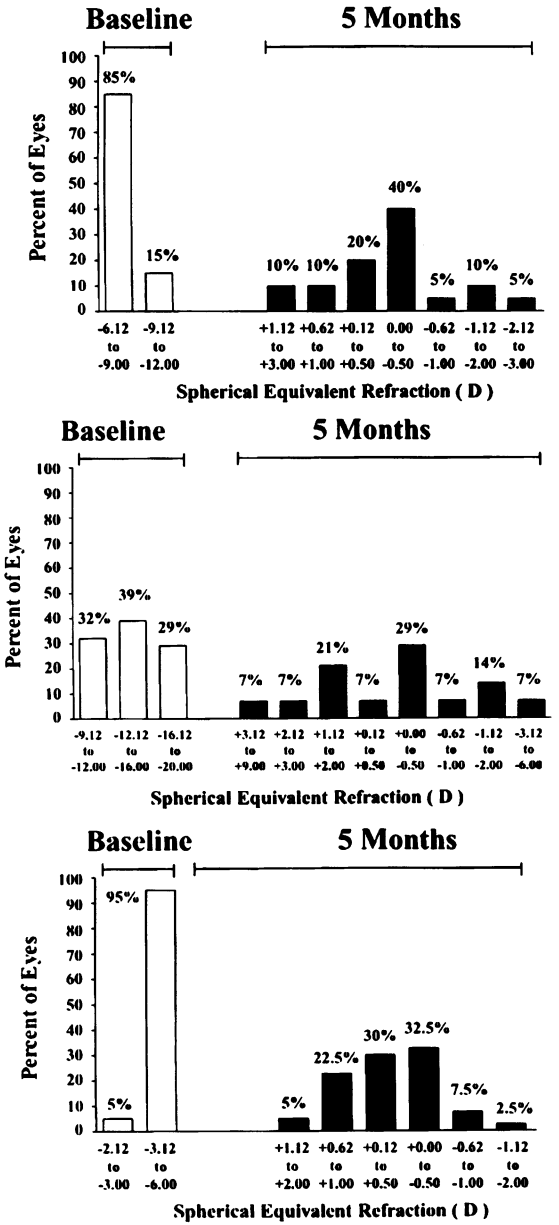

FIGURE 8

Bar graphs displaying spherical equivalent of manifest refraction in 88 eyes at mean of 5 months after LASIK in three baseline refractive groups: lower group of 40 eyes (top left), middle group of 29 eyes (top right), and higher group of 19 eyes (bottom left). Heights of bars represent percent of eyes in each range of refraction. (Table I presents refractive outcome for all eyes.)

TABLE II: CHANGE IN REFRACTIVE CYLINDER (D) FROM BASELINE TO MEAN OF 5 MONTHS AFTER LASIK IN 87 MYOPIC EYES

CHANGE IN REFRACTIVE CYLINDER (D)	NO. OF EYES (%)
Decrease	
2.00	1 (1.1)
1.75	0 (0.0)
1.50	4 (4.5)
1.25	2 (2.3)
1.00	7 (8.0)
0.75	10 (11.4)
0.50	12 (13.6)
0.25	14 (15.9)
No change	15 (17.0)
Increase	
0.25	6 (6.8)
0.50	11 (12.5)
0.75	4 (4.5)
1.00	0 (0.0)
1.25	2 (2.3)

TABLE III: SURGICALLY INDUCED REFRACTIVE ASTIGMATISM (VECTOR ANALYSIS, D) IN 87 MYOPIC EYES AT MEAN OF 5 MONTHS AFTER LASIK

INDUCED ASTIGMATISM (D)	NO. OF EYES	(%)
0.00 to 0.25	18	(20.7)
0.26 to 0.50	24	(27.6)
0.51 to 0.75	15	(17.2)
0.76 to 1.00	10	(11.5)
1.01 to 1.50	11	(12.6)
1.51 to 2.00	2	(2.3)
2.01 to 3.00	5	(5.7)
3.01 to 4.00	0	(0.0)
4.01 to 5.00	1	(1.1)
5.01 to 6.00	1	(1.1)
Mean (SD) 0.81 (0.86)		

TABLE IV: POSTOPERATIVE REFRACTIVE ASTIGMATISM (D) IN 87 MYOPIC EYES AT MEAN OF 5 MONTHS AFTER LASIK

ASTIGMATISM	NO. OF EYES	(%)
0.00	25	(28.4)
0.25	6	(6.8)
0.50	17	(19.3)
0.75	12	(13.6)
1.00	10	(11.4)
1.25	5	(5.7)
1.50	5	(5.7)
1.75	3	(3.4)
2.00	2	(2.3)
2.25	1	(1.1)
2.50	0	(0.0)
2.75	0	(0.0)
3.00	1	(1.1)
4.00	1	(1.1)
Mean (SD) 0.70 (0.72)		

VISUAL ACUITY OUTCOME

Uncorrected visual acuity at baseline was 20/200 or worse in 78 eyes (88.6%) and 20/50 to 20/100 in 10 eyes (11.4%) (Table V). Spectacle-corrected visual acuity before LASIK demonstrated that 9 eyes (10.2%) saw worse than 20/40 because of myopic chorioretinal degeneration; these poorer baseline values reduced the overall levels of uncorrected visual acuity after surgery. The change in spectacle corrected visual acuity from baseline to a mean of 5 months after surgery is presented in Fig 9; three eyes (3.4%) lost two or more Snellen lines.

For the three baseline refractive groups the uncorrected visual acuity outcome was as follows:

- Lower group (-2.00 to -6.00 D, 40 eyes): 20/20 or better, 28 eyes (68.4%); 20/25 to 20/40, 10 eyes (26.4%); 20/50 to 20/100, 2 eyes (5.3%); and 20/200 or worse, zero.
- Middle group (-6.10 to -12.00 D, 29 eyes): 20/20 or better, 5 eyes (17.5%); 20/25 to 20/40, 13 eyes (44.8%); 20/50 to 20/100, 10 eyes (34.5%); and 20/200 or worse, 1 (3.4%).
- Higher group (-12.00 to -20.00 D, 19 eyes): 20/20 or better, zero; 20/25 to

TABLE V: VISUAL ACUITY AT BASELINE AND AT MEAN OF 5 MONTHS AFTER LASIK FOR MYOPIA

SNELLEN VISUAL ACUITY	SPECTACLE CORRECTED		UNCORRECTED	
	BEFORE SURGERY NO. OF EYES(%)	AFTER SURGERY NO. OF EYES(%)	BEFORE SURGERY NO. OF EYES(%)	AFTER SURGERY NO. OF EYES (%)
20/20 or better	37 (42.5)	37 (44.6)	0 (0.0)	31 (36.0)
20/25 - 20/40	41 (47.0)	36 (43.4)	0 (0.0)	30 (34.8)
20/50 - 20/100	7 (8.0)	8 (9.6)	10 (11.4)	21 (24.4)
20/200 or worse	2 (2.2)	2 (2.4)	78 (88.6)	4 (4.7)
Total	**87 (100.0)**	**83 (100.0)**	**88 (100.0)**	**85 (100.0)**

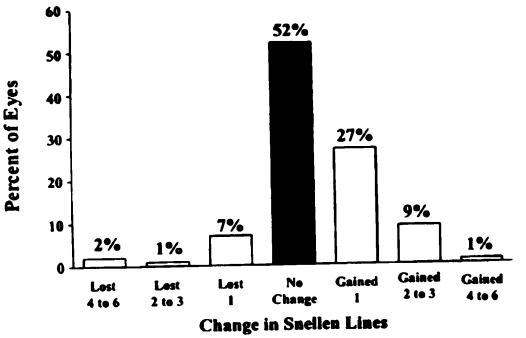

FIGURE 9

Bar graph showing change in spectable-corrected visual acuity in 88 eyes between baseline and 5 months after LASIK. Change is expressed as gain or loss in Snellen lines.

20/40, 7 eyes (36.8%); 20/50 to 20/100, 9 eyes (47.5%); and 20/200 or worse, 3 eyes (15.8%).

PREDICTABILITY

The predictability of the technique can be estimated by the range of refraction within which 90% of the eyes fell; the goal was emmetropia in all eyes. The refraction for 90% of the eyes was from -1.25 D to +1.63 D, a range of 2.88 D.

SYMMETRY OF REFRACTIVE OUTCOME

In 32 of 63 patients (50.8%), both eyes were operated on at the same surgical session by the same surgeon using the same instruments and operating on the right eye first. This subgroup allowed us to estimate how repeatable

the surgical technique was. At baseline, the mean refraction for these 32 patients was: RE, -9.45 (SD, 4.66; range, -3.75 to -18.37 D) and LE, -9.14 (SD, 4.54; range, -3.50 to -19.12 D) for a mean difference of 0.31 D (SD, 1.87; range, +5.87 to -4.87 D). At 5 months, the right eyes had a mean refractive outcome of +0.25 D (SD, 1.58; range, -3.25 to +6.00 D) and the left eyes a mean refractive outcome of +0.29 D (SD, 1.61; range, -3.60 to +6.75 D). The absolute difference in the spherical equivalent of the manifest refraction between the two eyes was a mean of 0.71 D (SD, 0.72; range, 0.00 to 2.50 D). Table VI presents the symmetry of outcome for these 32 patients.

TABLE VI: SYMMETRY OF SPHERICAL EQUIVALENT REFRACTION IN 32 PATIENTS AT A MEAN OF 5 MONTHS AFTER BILATERAL LASIK FOR MYOPIA.

DIFFERENCE IN REFRACTION BETWEEN TWO EYES (D)	NO. OF PATIENTS (%)	
	BASELINE*	AFTER LASIK*
0.00 to 0.50	20 (62.5)	17 (53.1)
0.62 to 1.00	5 (15.6)	9 (28.1)
1.00 to 2.00	2 (6.2)	3 (9.4)
2.01 to 5.87	5 (15.6)	3 (9.4)
Total	**32 (100.0)**	**32 (100.0)**

* $P < .05$, paired *t test*.

STABILITY

We estimated the stability of refraction during the 5-month follow-up by comparing the refraction at an earlier visit (mean, 3 weeks; range, 5 to 54 days) to that at a later visit (mean, 5.3 months; range, 91 to 253 days). Sixty-five of 88 eyes (73.9%) were examined at both intervals. There were clinically meaningful changes in refraction between 3 weeks and 5 months. From 3 weeks to 5 months the refraction in 32 eyes (49.2%) changed by less than 1.00 D; 19 eyes (29.2%) shifted toward myopia by -1.00 to -1.90 D; 10 eyes (15.4%) shifted toward myopia by -2.00 to -4.00 D; and 4 eyes (6.2%) shifted toward hyperopia by +1.00 to +2.75 D.

There was a trend toward overcorrection at 3 weeks with a mean refraction of +0.79 D (SD, 1.89; range, -7.88 to +8.00), with 21 eyes (32%) overcorrected by more than +1.00 D and 4 eyes (6%) undercorrected by more than -1.00 D. By 5 months the mean refraction had decreased to +0.22 D (SD, 1.42; range, -4.75 to +6.75 D), with 15 eyes (23%) overcorrected by more than +1.00 D and 10 eyes (15.4%) undercorrected by more than -1.00 D.

Change in mean central keratometric power from 37.25 D (SD, 3.07; range, 32.25 to 46.12 D) at 3 weeks to 37.89 D (SD, 2.80; range, 31.00 to 43.50 D) at 5 months indicated average corneal steepening, which corresponded to the decreasing hyperopia and decreasing number of overcorrections.

COMPLICATIONS

Surgical Complications

Three eyes did not have a vertex distance conversion preoperatively. Three eyes had a complete severing of the disc from the bed, two being sutured back in place and one being repositioned without sutures; the postoperative course of these three eyes did not differ from the eyes with a hinged flap. In three eyes, the microkeratome stopper jammed on the suction ring and would not reverse, requiring removal of the two instruments together, without untoward effects on the cornea.

Loss of Spectacle-Corrected Visual Acuity

Three eyes lost two or more lines of spectacle corrected visual acuity. Two eyes of a 41-year-old patient with preoperative myopic macular degeneration (Fuchs' spot) lost spectacle-corrected visual acuity from preoperative levels of 20/40 in the right eye and 20/30 in the left eye to postoperative levels of 20/100 in both eyes, because of progression of the maculopathy. Contact lens overrefraction did not improve visual acuity. One other eye lost two lines of spectacle-corrected visual acuity from 20/20 preoperatively to 20/30 postoperatively because of mild induced irregular compound hyperopic astigmatism (+2.00 -1.00 x 37°).

Changes in the Cornea

With slit-lamp microscopy, fine wrinkles in the flap could be seen with broad tangential and retro-illumination, but the incidence was not recorded. The wrinkles were faint (resembling fingerprint lines), were confined to the flap, and were thought unlikely to affect visual acuity. Small amounts of debris were seen in the interface of some corneas, including metallic particles from the instrument, fine fibers, and small punctate matter; none was severe enough to affect visual acuity.

Repeated LASIK for Undercorrection

One patient had a preoperative manifest refraction of -3.75 -0.75 x 70 (20/15) in the right eye and -4.00 -0.25 x 150 (20/20) in the left. Three months after bilateral simultaneous uncomplicated LASIK, the uncorrected visual acuity was 20/70 RE and 20/20 LE. Manifest refraction was -4.25 D RE (20/20) and +1.00 D LE (20/20). Videokeratography in the right eye was nearly unchanged from preoperatively, and in the left eye there was a circular zone of central flattening displaced slightly nasally. The reason for the

lack of effect in the right eye was unknown. Four months after surgery a repeat LASIK was carried out in the right eye by lifting the flap and performing a repeated ablation for -4.00 D with a 6.00-mm diameter zone and a depth of 54 μm using 217 pulses. One month after the repeated surgery, visual acuity without correction was 20/25 and the manifest refraction was plano -1.50 x 30° - 20/20. Videokeratography in the right eye showed central flattening with slight horseshoe shape.

Complications Not Seen

The following potential complications did not occur in this series: perforation of the cornea during surgery, gross decentration of the flap or ablation, epithelial implantation in the bed, dislocation of the flap or disc postoperatively, and microbial keratitis.

DISCUSSION

LASIK under an anterior corneal flap combines the strengths of intrastromal refractive surgery achieved by a microkeratome section of the cornea with the sphero- cylindrical refractive correction achieved by an excimer laser ablation, advantages emphasized by Pallikaris and Siganos,[10] Salah and associates,[11] and Ruiz and coworkers.[14]

SURGICAL CONSIDERATIONS

Because both the microkeratome and the excimer laser are reasonably automated (Fig 1), the surgeons in this study and others at our institution readily acquired the skill of performing LASIK in a reliable and repeatable manner. We had no serious surgery-related complications in this series. However, once the microkeratome begins to progress across the cornea and once the excimer laser begins its ablation, the surgeon cannot judge the extent of cutting or ablation of the cornea and therefore does not have delicate intraoperative control of the processes; thus the instruments must be calibrated and tested before surgery. Both instruments are expensive to purchase, require meticulous maintenance by trained personnel, have ongoing expensive disposables (gas, blades), and are in the midst of rapid technical change and development with inevitable obsolescence of previous models and the need for retraining of personnel.

The hinged corneal flap reduces surgical time because of the speed of folding back the flap. We think it reduces astigmatism because it can be reapproximated to its original position by floating it back into position on a layer of balanced salt solution without sutures. The dimensions and centration of flap do not have to be exact, since the refractive effect is achieved by the excimer laser ablation in the bed and not by flap. Should the flap become dislocated after surgery, it remains attached to the cornea, allowing it to be repositioned.

VERSATILITY AND ACCURACY OF REFRACTIVE CORRECTION

In this series, LASIK corrected between -2.00 and -20.00 D with a single technique, an advantage for simplicity. This range of correction is difficult to achieve with other refractive corneal surgical procedures; most achieve a refractive outcome within ±1.00 D of emmetropia in less than 50% of eyes (Table VII), whereas we achieved this result in 73% (Table I), and Pallikaris and Siganos[10] in 6 of 10 eyes (67%). In addition, the results of LASIK reported here in eyes with -2.00 to -6.00 D (63% within ±0.50 D and 93%

TABLE VII: COMPARISON OF REFRACTIVE OUTCOME OF CORNEAL SURGICAL PROCEDURES FOR MYOPIA OF APPROXIMATELY -2.00 TO -20.00 D.

SURGICAL TECHNIQUE	FIRST AUTHOR	RANGE (MEAN) OF PREOPERATIVE REFRACTION (D)*	FOLLOW-UP TIME (YR)	NO. OF EYES	NO. OF EYES (%) WITHIN ±1.00 D*
Barraquer cryolathe keratomileusis	Nordan[30]	-4.25 to -14.00 (-8.51)	1.0	74	38 (51)
BKS 1000 nonfreeze keratomileusis	Laroche[4]	-6.25 to -28.00 (-14.24)	1.0	82	21 (26)
Corneal shaper automated in situ keratomileusis (ALK)	Ibrahim†	-3.75 to -28.00 (-11.97)	1.0	63	22 (35)
Refractive keratotomy (deepening incisions) (RK)	Bauerberg[31]	-6.00 to -12.00 (-7.83)	1.0	167	97 (58)
VISX 20/15 excimer laser photorefractive keratectomy (PRK)	Sher[32]	-8.00 to 15.00 (-11.18)	0.5	48	20 (40)
Summit excimer laser keratomileusis on the disc	Burrato[8]	-11.20 to -24.50 (-17.90)	1.0	30	13 (43)
Aesculap-Meditec excimer laser in situ keratomileusis (LASIK)	Pallikaris[10]	-10.62 to 25.87 (-16.61)	1.0	10	6 (67)
Summit excimer laser in situ keratomileusis (LASIK)	Salah (present study)	-2.00 to -20.00 (-8.24)	0.5	88	64 (73)

*Spherical equivalent refraction.
†Ibrahim O, Waring III GO, Salah T, El Maghraby A. Automated in-situ keratomileusis for myopia. Unpublished data.

within ±1.00 D, Fig 3) are similar to those reported for photorefractive keratectomy[15-17] (eg, Epstein and colleagues[16] reported 72% of 495 eyes within ±0.50 D and 88% within ±1.00 D at 2 years) and refractive keratotomy[18,19] (eg, the Casebeer/Chiron study[19] reported 63% of 546 eyes within ± 0.50 D and 94% within ±1.00 D at 1 year). As the technology of excimer lasers for corneal surgery develops the ability to achieve more physiologic aspheric corneal contours with gradually sloping and tapered edges over a large diameter,[20,21] LASIK should improve in its ability to correct a full range of myopia and, theoretically, both astigmatism and hyperopia.

Approximately half of our patients had both eyes operated on at the same surgical session under virtually identical conditions for each eye, and the symmetry of outcome was good; in fact, the mean difference in refraction between the two eyes of an individual patient was less than that present preoperatively (Table VI). This suggests that the procedure is reasonably repeatable.

Although the results with LASIK reported here reached a level of clinical acceptability in our opinion, the algorithms used in this study need modification because of the wide standard deviation of refractive outcome of 1.42 D, the mean overcorrection of +0.22 D, and the presence of 14 eyes (16%) overcorrected by more than +1.00 D (Table I, Figs 2 and 3). This can be partially achieved by subtracting approximately 0.50 D from the spherical equivalent refraction corrected to the corneal plane prior to entering it into the computer when using the Summit PRK algorithm, which has the advantage of using a 6.0- to 6.5-mm-diameter ablation zone. We are modifiying the Salah-LASIK nomogram used in this study (see Appendix). This nomogram uses a 4.5- to 5.0-mm-diameter ablation zone, which might create optical aberrations over a large pupil.

SHORT-TERM STABILITY OF REFRACTION

There was an early mean overcorrection followed by a myopic shift during the 5 months of follow-up — 15%, shifting by 2.00 to 4.00 D. The frequency and duration of our postoperative follow-up did not allow determination of when this myopic shift occurred. Longer follow-up will determine when refraction stabilizes after LASIK.

THEORETICAL EFFECT OF STROMAL WOUND HEALING ON REFRACTIVE OUTCOME

Various techniques of keratomileusis have been done on humans since 1963.[1-11] One of the most remarkable findings is that an uncomplicated keratomileusis results in virtually no stromal opacification at the interface of the anterior disc and the bed, because there is minimal production of new extracellular matrix in this area, as documented histopathologically.[22-25] Clinically, the location of the interface is usually revealed by a few foreign particles. Light microscopy shows no discontinuity between the disc and the bed, although transmission electron microscopy reveals the deposit of basement mem-

brane–like material and a nonuniform lamellar structure at the interface. This minimal stromal wound healing theoretically makes it possible to alter corneal stromal curvature and to have that shape persist indefinitely, without the active remodelling or fill-in that occurs after photorefractive keratectomy.[21,26] In our LASIK series, the lamellar bed remained clear except for some particulate matter and at 6 to 12 weeks focal grey "healing spots" that were approximately 0.1 mm in diameter and gradually faded with time. We administered no topical corticosteroids because we thought there was no need to suppress inflammation or to modulate stromal wound healing by decreasing fibroblast activity. Thus, we think LASIK may offer greater predictability and stability than photorefractive keratectomy and refractive keratotomy, where variations in individual wound healing can substantially affect the refractive outcome.[20,21,27] Proof of this contention will require prospective randomized trials.

SAFETY

The fact that only one eye lost two or more lines of spectacle-corrected visual acuity from the procedure (because of the irregular astigmatism) demonstrates that LASIK was safe in this small series. Of course, serious complications not seen in our series can occur, such as (1) the base plate is not installed in the microkeratome, which will result in perforation of the cornea; (2) the microkeratome pass is irregular and creates irregular astigmatism or scarring; (3) the flap or disc is too thin, which can create scarring in the bed; (4) the flap becomes dislocated after surgery with resultant stromal scarring; (5) epithelial implantation and growth occurs; (6) microbial keratitis occurs; (7) glare or halos present a significant functional problem for the patient.

MINIMAL INDUCTION OF ASTIGMATISM

One concern in using microkeratome techniques for refractive surgery is that the creation of an anterior corneal disc or flap will inevitably increase regular or irregular astigmatism. Concerning regular astigmatism, we demonstrated a decrease in the mean refractive astigmatism of approximately 0.20 D (Table II) and a mean change in vector corrected astigmatism of 0.81 D (Table III). We think that these small changes in regular astigmatism were acceptable.

The presence of clinically meaningful irregular astigmatism after LASIK can be estimated by the change in spectacle-corrected visual acuity, especially since corneal haze was not present. Since only one eye lost two or more lines of spectacle-corrected visual acuity from the procedure, we do not think that clinically meaningful amounts of irregular astigmatism were produced. However, in a separate series of eyes that received LASIK, videokeratography demonstrated some central steep areas and irregularity, with an increase in the surface regularity index over the pupil and other

indices described by Wilson and Klyce[28] (Waring GO III, Salah T, Klyce SD, et al. Corneal topography after excimer laser in-situ keratomileusis. Unpublished data).

MINIMAL PAIN AND RAPID RECOVERY OF USUAL VISUAL ACUITY AFTER SURGERY

Although we did not quantify postoperative pain and the rate of the recovery of visual acuity in this study, our patients complained of minimal pain and we administered no topical corticosteroids, nonsteroidal anti-inflammatory agents, or oral analgesics, as is commonly done after photorefractive keratectomy[29] and refractive keratotomy. Within 24 hours after surgery, the majority of patients had functional visual acuity and carried on ordinary daily activities.

REPEATED REFRACTIVE SURGERY

The ideal refractive surgical procedure is adjustable. Eyes that remain undercorrected after LASIK can have a second LASIK procedure; the corneal flap is simply lifted and another ablation performed in the bed (case report in this paper and Salah T, Waring GO III, et al. Repeated excimer laser in-situ keratomileusis. Unpublished data in 10 eyes). It is also possible to perform radial keratotomy, transverse keratotomy, or photorefractive keratectomy for undercorrection after LASIK (Salah T et al. Unpublished data).

PRESENT STATUS OF LASER IN SITU KERATOMILEUSIS (LASIK)

We think the LASIK procedure represents an improvement over other types of refractive corneal surgery (Table VII), but there is a need to document this opinion in prospective clinical trials of the procedure itself and in prospective randomized trials of different procedures. Continued refinements in the design and function of microkeratomes and excimer lasers and in surgical nomograms may improve the predictability of refractive outcome.

REFERENCES

1. Barraquer J: Queratomileusis para la correccion de la miopia. *Arch Soc Am Oftalmol Optom* 1964; 5:27-48.
2. Barraquer J: *Cirugia Refractive de la Cornea*. Bogota, Columbia, Instituto Barraquer de America, 1989.
3. Pureskin N: Weaking ocular refraction by means of partial stromectomy of the cornea under experimental conditions. *Vestn Oftalmol* 1967; 80:1-10.
4. Laroche L, Gauthier L, Thenot JC, et al: Nonfreeze myopic keratomileusis for myopia in 158 eyes. *J Refract Corneal Surg* 1994; 10:400-12.
5. Schuler A, Jessen K, Hoffman F: Accuracy of the microkeratome keratectomies in pig eyes. *Invest Ophthalmol Vis Sci* 1990; 31:2022-2030.
6. Arenas-Archilla E, Sanchez-Thorin J, Naranzo-Uribe J, et al: Myopic keratomileusis in-situ: a preliminary report. *J Cataract Refract Surg* 1991; 17:424-435.
7. Ruiz J, Rowsey J: In-situ keratomileusis. *Invest Ophthalmol Vis Sci* 1989; 29(suppl):392.
8. Burrato L, Ferrari M, Genesi C: Myopic keratomileusis with the excimer laser. One-

year follow up. *J Refract Corneal Surg* 1993; 9:12-19.
9. Pallikaris I, Papatsanaki M, Stathi E, et al: Laser in-situ keratomileusis. *Lasers Surg Med* 1990; 10:463-468.
10. Pallikaris IG, Siganos DS: Excimer laser in-situ keratomileusis (LASIK) versus photorefractive keratectomy for the correction of high myopia. *J Refract Corneal Surg* 1994; 10:1-13.
11. Salah T, Waring GO, El-Maghraby A: Excimer laser keratomileusis. Part I. In: Salz JJ, ed. *Corneal Laser Surgery*. St Louis, Mosby-Year Book, 1995, pp 187-194.
12. Waring GO: Standardized Data Collection and Reporting for Refractive Surgery. *J Refract Corneal Surg* 1992; 8(suppl):1-45.
13. Naylor EJ: Astigmatic difference in refractive errors. *Br J Ophthalmol* 1968; 52:422-425.
14. Ruiz L, Slade SG, Updegraff SA: Excimer myopic keratomileusis: Bogota experience. In: Salz JJ, ed. *Corneal Laser Surgery*. St Louis, Mosby-Year Book, 1995, p 195.
15. Maguen E, Salz J, Nesburn A, et al. Results of excimer laser photorefractive keratectomy for the correction of myopia. *Ophthalmology* 1994; 101:1548-1156.
16. Epstein D, Fagerholm P, Hamberg-Nystrom H, et al: Twenty-four month follow-up of excimer laser photorefractive keratectomy for myopia. *Ophthalmology* 1994; 101:1558-1563.
17. Seiler T, Wollensak J: Myopic photorefractive keratectomy with the excimer laser. One year follow-up. *Ophthalmology* 1991; 98:1156-1163.
18. Waring GO, Lindstrom KK: Results of refractive keratotomy. In: Waring GO, ed. *Refractive Keratotomy for Myopia and Astigmatism*. St Louis, Mosby-Year Book, 1992, pp 781-848.
19. Waring GO, Casebeer JC, Gordon JF, et al: A prospective multicenter study of refractive keratotomy for myopia and astigmatism. *Ophthalmology* 1994; 101(Suppl):90.
20. Maguen E, Machat JJ: Complications of photorefractive keratectomy, primarily with the VISX excimer laser. In: Salz JJ, ed. *Corneal Laser Surgery*. St Louis, Mosby-Year Book, 1995, pp 143-158.
21. Krueger RR, Binder PS, McDonnell PJ: The effects of excimer laser photoablation on the cornea. In: Salz JJ, ed. *Corneal Laser Surgery*. St Louis, Mosby-Year Book, 1995, pp 11-44.
22. Baumgartner SD, Binder PS: Refractive keratoplasty. Histopathology of clinical specimens. *Ophthalmology* 1985; 92:1606-1616.
23. Jacobiec FA, Koch P, Iwamoto T, et al: Keratophakia and keratomileusis. Comparison of pathologic features in penetrating keratoplasty specimens. *Ophthalmology* 1981; 88:1251-1259.
24. Jester JV, Rodriguez MM, Villasenor RA, et al: Keratophakia and keratomileusis: Histopathologic, ultrastructural, and experimental studies. *Ophthalmology* 1984; 91:793-805.
25. Yamaguchi R, Freidlander MH, Kimura T, et al: The ultrastructure of well-healed lenticules in keratomileusis. *Ophthalmology* 1983; 91:1495-1506.
26. SundarRaj N, Geiss MJ, Fantes F, et al: Healing of excimer laser ablated monkey corneas: An immunohistochemical evaluation. *Arch Ophthalmol* 1990; 108:1604-1610.
27. Waring GO, Lynn MJ, McDonnell PJ, et al: Results of the Prospective Evaluation of Radial Keratotomy (PERK) study 10 years after surgery. *Arch Ophthalmol* 1994; 112:1298-1308.
28. Wilson SE, Klyce SD: Quantitative descriptors of corneal topography: A clinical study. *Arch Ophthalmol* 1991; 109:349-353.
29. Sher NA, Frantz JM, Talley A, et al: Topical diclofenac in the treatment of ocular pain after excimer photorefractive keratectomy. *J Refract Corneal Surg* 1993; 9:425-436.
30. Nordan LT, Fallor MK: Myopic keratomileusis: 74 consecutive non-amblyopic cases with one year of follow-up. *J Refract Corneal Surg* 1986; 2:124-128.
31. Bauerberg J, Styzovsky M, Brodsky M: Radial keratotomy in myopia of 6 to 12 diopters using full-length deepening incisions. *J Refract Corneal Surg* 1989; 5:150-154.
32. Sher NA, Hardten DR, Fundingsland B, et al: 193-nm excimer photorefractive keratectomy in high myopia. *Ophthalmology* 1994; 101:1575-1582.

DISCUSSION

DR ROBERT C. DREWS. Dr Waring has given us an intriguing and well-presented study. Like many retrospective studies, one major problem is loss to follow-up. Sixty-eight percent of the patients (133 of 196) and 74% of the eyes (249 of 337) that had a LASIK procedure had inadequate follow-up and could not be included. Over half simply didn't return when they should have. This loss to follow-up rate is too great to allow firm conclusions. We tend to infer that patients who don't come back are doing as well as the ones we see. But 93% of the 2,000 intraocular lenses Apple studied were removed and submitted by surgeons who had not put them in.

Although the average refractive error after surgery was commendable (0.22 diopters), 10% of the eyes had more that ±1.5 diopters of error. That, plus uncorrected astigmatism of up to 4 diopters may explain why the final uncorrected visual acuity was not better. To test reproducibility, the same surgeon operated on both eyes at the same time using the same technique, but differences of up to 2.5 diopters in results are reported. One patient who was 4 diopters myopic in both eyes got no correction at all in one eye and 5 diopters of correction in the other. Reoperation on the first eye was successful, but there had been a 5-diopter difference.

Figure 7 of the paper shows that there were two patients with large overcorrections. One appears to have gone from -19.00 diopters to +8.00, and the other from -15.00 diopters to ±5.00. It seems to me that these represent major problems. While the procedure is a technical tour de force and, considering the difficulty, yields remarkably good results, it might be surprisingly disappointing to some patients, especially patients who are hyperopic postoperatively or who have 5 diopters of anisometropia.

It is good to see that there was no progression toward hyperopia. There was a mild myopic progression instead, but follow-up is too short to be sure about this. Mild? The myopic shift can be considerable: 15% of the patients shifted 2 to 4 diopters.

Was the progression of the myopic macular degeneration in both eyes of one patient, within months of the surgery, aggravated by the surgery? If the patient were in the United States, she might assume it was.

The finding of debris in the interface after lamellar keratoplasty is an old one. Ultrasonic cleansing of instruments, filtered laminar airflow across the operating field, and millipore filtration of all fluids used during surgery may help to reduce this.

This surgery uses high-tech, very expensive equipment. The authors state that there were no serious surgery-related complications, but having the instrument get stuck during use, or accidentally slicing off the entire lamellar button might call forth a few (hopefully unspoken) expletives.

In these less golden times, we see once-firm ethical foundations shifting. The Academy is obliged to serve its members by allying with a major

fast-service optical chain. Manufacturers spend major funds persuading the public that costly miracles are needful and physicians join in reaping the harvest of the new demand. What is best for the patient sometimes becomes what the market can be persuaded to desire.

Twelve years ago I used a YAG laser for the first time, at a meeting in the Netherlands. I watched in amazement as I did with delicate control what would have been otherwise crude, sometimes impossible. I bought one on the spot. In contrast, refractive surgery results don't always fit the hype. In this study, three of the patients who had follow-up lost vision. Not many, you say? These were not diseased eyes in need of treatment, where one weighs significant risks of lack of care against smaller risks of therapy. "I will do no harm to those entrusted to my care."

Do not misinterpret my words as a reproval for the careful work that Dr Waring and his colleagues have done. But many of us worry about the trends we see around us. Twenty million Americans should rush for refractive surgery? I am not so sure. A few diopters of myopia at my age are a godsend for me.

Excimer refractive procedures continue to improve. We have seen modifications in delivery strategies, and now the use of the excimer in an invasive procedure that preserves the corneal surface. Lack of pain and more rapid recovery of vision are major advantages. Are the results enough better to require the extra effort? Probably, but conclusions regarding the relative safety and efficacy of this procedure must await a prospective study with minimum loss to follow-up.

We thank the authors for this interesting paper.

DR. VERINDER NIRANKARI. I want to congratulate George for this wonderful paper. I have a question and one comment. Did they compare their results with the recently published paper that was presented last year at the AOS by Dr Hugh Taylor and his associates from Australia? And if I recall, they were also looking at high myopes. Their result of PRK as I recall was that almost 90% of patients in the high myopia group were within plus or minus one diopter which seems pretty remarkable and the patients who had extreme myopia (12-20 diopters), at least 50% of them were also within one plus or minus one diopter. The main problem they had was regression in some and corneal haze, but in the final results they had about six months of haze that gradually disappeared. In their group of myopes, only about 11% of the patients had a loss of vision at approximately two months. So I am just wondering if you can put this into perspective about LASIK when compared to PRK in treatment of high and extreme myopia. When I was in Bogota recently, where the ophthalmologists are doing ALK and LASIK and these seem to be the procedures of choice. It was amazing to see Dr Ruiz who is one of the real fine surgeons doing 60 cases in about six hours while I was there and he got patients from minus a half to minus 38 diopters

to be close to emmetropia. And what was amazing is that he treats patients with myopia, hyperopia, astigmatism and presbyopia with the LASIK procedure. My final question is, and this is really what is happening to Excimer in this country is purely economics. Just the Excimer itself is cost-prohibitive. Will ophthalmologists a group be able to consider some kind of collective arrangement to set up refractive centers that are ophthalmologically controlled or is it to be controlled by corporate interests or optometry!

DR. RICHARD FORSTER. I really enjoyed Dr Waring's paper. I especially reminisced on my experiences in Saudi Arabia, since I had spent nearly five years in Riyadh as Medical Director of the King Khaled Eye Specialist Hospital. I have some questions for you, George.

First, you didn't tell us how you developed the nomogram for your study. Was this one that you inherited from the developer of the technique, or did these patients actually go through personal analysis permitting you to develop and modify the nomogram? Presumably, in a retrospective study, the early cases of higher myopia would reflect less desirable results.

In addition, I was somewhat surprised by the limited follow-up of your study. When I first went to Saudi Arabia, I was under the impression that follow-up of patients would be a major problem, but in fact, I became impressed that the follow-up was much better than I had anticipated, since the Saudi government in most cases provided transportation for the patient and accompanying family member for follow-up visits, and it was unusual that a patient didn't meet their expected follow-up visit, unless they had illness or a death in the family. I wonder if you could tell us how patients were recruited, and a little bit about the follow-up and why it wasn't better?

Thirdly, while in Saudi Arabia, I was impressed with the fact that there seems to be a low prevalence of macular disease, certainly age related maculopathy, and I wonder if you could tell us more about the ages of the patients that you recruited. Did they have good preoperative refraction and a defined level of best corrected vision, and to what level of correction were they required to see before undergoing the procedure? Did you attempt to rule out amblyopia, since in a group of patients with relatively high myopia you would suspect a certain prevalence of amblyopia. Finally, in the postoperative results, what was the role of irregular astigmatism, and was there an attempt to correct the patients with a contact lens to determine their best visual acuity? Was the decrease in vision due to unrecognized, pre-existent maculopathy or amblyopia, or was it due to irregular astigmatism?

I enjoyed your paper, George, and again, share a lot of your feelings about the country.

DR WILLIAM BOURNE. I would like to congratulate Dr Waring on his study and his attempts to improve the vision of Saudi people, where glare and bright sun are a particular problem.

I have two questions, and George and I have talked about this. I imagine there is a reason why ALK where no laser is used should have so much more irregular astigmatism than LASIK. In both there is no violation of central Bowman's membrane. But in the LASIK there doesn't appear to be this irregular astigmatism which is a big problem in the ALK - so much so that at last week's ARVO meeting Dr Waring suggested quite correctly that maybe that procedure shouldn't be done anymore until we find out what the longer term results are.

My second question is about damage to the endothelium. This is always a question with this procedure because most of the time studies have shown that the laser doesn't seem to affect the central endothelium when it is done superficially, but when it is deep in the bed, particularly within one to two hundred microns of the endothelium, there definitely is damage. Lasering in the bed, especially in high myopes, I think you do get this close to the endothelium. I am wondering if any studies on the central endothelium are being done? This also raises the question, why not do the laser on the cap and avoid any laser damage to the endothelium? This would require a deeper path and also has problems with the centering of the eye.

Once again I congratulate George on his work.

DR. GEORGE STERN. I want to congratulate George on this very important study. As I read the refractive surgery literature, I have a great deal of difficulty with what amounts to a comparison of "apples and oranges", where we are dealing with different surgical procedures, intersurgeon variabilities with the same procedure, and different ranges of refractive errors, and I am having the same difficulty today after hearing George's paper. There are now a number of refractive surgery procedures available, and the practicing ophthalmologist finds him/herself asking "Which procedure should I do?". Studies to date have confined themselves to the question of "Do these procedures work?". The PERK and other studies showed that RK works, the FDA studies have shown that the excimer laser works, we hear a lot about ALK, and now George's paper has shown us that LASIK works. The question that comes to mind is "which is better?". It is hard for me to answer that question from the data George has given us. He described treating a refractive range from -2D to -20D and compared that to other studies treating -2 to -6. I didn't get a feeling from his presentation how many of his patients were in the -6 to -20 range and how that might have affected the comparison. Another significant concern is the length of follow-up and amount of regression, and I didn't get a feeling for the percent of patients who were followed up long term, and the length of follow-up for those patients who were followed. Can you give us some historical data about this aspect of the procedure, if not your own data? The last question I have relates to the loss of best corrected acuity, which is a very serious concern. I know that George was intimately involved with the PERK study and probably remembers the

data much better than I do, but I was under the impression that the loss of two or more lines of best corrected acuity was more on the order of 0.5% in the PERK study, and not 3.6% which I believe is more on the order of what the FDA found with the excimer laser.

This was a very nice study and I look forward to hearing George's paper at the Academy comparing ALK to LASIK, because I think that these are the kind of studies we need at this point in time. Hopefully, in the future, someone will take that -2 to -6 group and prospectively compare these newer procedure to RK, which I don't think has been proven to be dead yet. Thank you.

DR. GEORGE WARING. Dr Drews and colleagues, thank you for your kind comments. Dr Drews notes that three eyes lost significant vision in our study, but two of these were from progression of myopic degeneration. Dr Drews stated that these "were not diseased eyes", but in those eyes in which there was myopic retinopathy, there was indeed disease. Only one eye lost vision directly related to the procedure - one with irregular astigmitism and over correction. We do not know whether the LASIK procedure caused the progression of the myopic degeneration, but I do not know a mechanism by which the two would be pathogenically related.

I agree fully with Dr Drews that 20/40 is not an adequate criterion for a refractive surgery outcome. Our criteria must be the same as spectacles - 20/20 or better.

I agree with Dr Drews that the loss of follow-up in our current study is greater than desired. We are now carrying out a prospective trial in the United States at the Emory Vision Correction Center under an FDA investigational device exemption of the LASIK procedure and we expect to have a very high rate of follow-up.

The major concern of all the discussants was the quality of follow-up in our study; the overall quality of our study was average in my opinion. It was retrospective; we had a high loss of follow-up; there was variability in surgical technique; and some of the other problems existed that people pointed out. The reason I presented this preliminary study to you is that it is one of the few current sources of information about LASIK. LASIK is having a period of popularity. It represents a basis on which we design our formal trial at Emory under the FDA IDE protocols and we need to know as much about it as possible. So I think we can look forward to more formal information that is more structured and doesn't have the deficiencies which bedevil this particular trial.

The follow-up in our trial was almost six months and therefore we can't present meaningful stability data. One of the advantages of the LASIK procedure is that wound healing plays less of a role than it does in refractive keratectomy or photorefractive keratectomy. There is no haze; stromal reaction is minimal in the bed. This something we have known for thirty years

since Jose Barraquer started doing keratomileusis. At a recent meeting there have been papers on epithelial-stromal interaction. There is communication between the epithelium and the stroma; if the epithelium is preserved, it doesn't send cytokine messages to the stromal keratocytes to tell them to convert to fibroblasts and commence wound healing. So the stroma is very passive in a keratomileusis procedure. I think this is one of the advantages of LASIK. Only follow-up of one to three, or more years is going to tell us how stable it really is compared to other procedures.

George Stern's comments about standardization of reporting results are close to my heart. I published a couple of years ago a set of standards for refractive surgery reports; the data represented here can be compared to other series. I think that adherence to reporting results, particularly since we have so many different refractive procedures, it is absolutely crucial to our ability to make sense out of them.

The biggest drawback from the technical point of view in our study was the algorithms for laser ablation that we used. We used two of them. One devised by Dr Salah from Dr Ruiz's work and the other devised by Summit for PRK which was the one that I used. The varied algorithms are probably the reason that we had outliers (as Dr Drews pointed out); we had four outliers in this population of 88 eyes; two grossly over corrected, two grossly undercorrected and I don't know why that happened in these cases. It could be the inherent variability in the procedure. But I believe as we use larger diameter of ablation zones (as we did in many of these eyes with six millimeters and multizone patterns to create more physiological contours of the cornea, we can use retrospective work such as these to adjust our algorithms to give us better results. I think we can look forward to better results in LASIK than I was able to report to you now.

The question of endothelial damage during LASIK is crucial; three of you asked about this. John Marshall presented experimental information a few years ago saying that the ablation had to be within 40 microns of the endothelium for the shock wave or the secondary radiation to damage the endothelium. We will have endothelial information 12 or 24 months from now from the American studies. We didn't do any endothelial cell counts in our study in Jeddah.

There is this question of whether or not the LASIK style of surgery might be able to correct all types of ametropia; I think in the future it will be possible. It is only a matter of adjusting the shape of the Eximer laser beam to correct hyperopia, astigmatism and myopia. So this is part of the technologic advance. Certainly there are a lot of disadvantages with this procedure. We have already talked about the expensive equipment and the fact that components and software are changing rapidly. We are concerned about inducing irregular astigmatism*. We did not do contact lens over refractions in these cases, but we should in questionable cases.

I am going to take the last couple of minutes and respond to the discus-

sants who asked about the business aspects of refractive surgery that are infecting our profession. The way to handle the business side is for ophthalmology to retain control of refrative surgery instead of business interests or optometry. And as long as we are passive, you can bet the business person and the optometrists will do the best they can to dominate this subspecialty, and we can't let them.

The way we have handled this in Atlanta is to realize that lots of ophthalmologists are going to be doing refractive surgery and that there are a lot of deficiencies in the way we provide refractive surgery; so we have set up our own refractive surgical center network in Atlanta with ophthalmology in control, The Vision Correction Group. We share costs. A couple of the discussants asked, how are you going to pay for these half-million dollar lasers? A microkeratome costs another $30,000. If you add a videokeratoscope that's another $50,000. Who is going to pay for all of this? We group together at the surgical center and we share costs. We have a dedicated facility, The Emory Vision Correction Center, where these unique refractive surgery patients, unique in the sense that they are upper income, have elective surgery that they can afford to pay for and are highly demanding. We don't mix them in with our cataract patients and the others with eye disease. The marketing to the public is vigorous and honest. There are no promises involving perfect vision without glasses. If you want accurate information come to The Emory Vision Correction Center and talk to the experts. We educate patients well. We educate them through individual counseling, through seminars, through literature, through physician consultation and through a multimedia touch screen computer kiosk. We train and credential our doctors and support them with skills transfer courses. We have a network of 150 optometrists throughout the area as a credentialed referral base for comanagement. We maintain quality standards.

I conclude by making this plug for ophthalmic control of refractive surgery.

*We quantified video keratography in these cases and found minimal central irregularity.